K122252

Medical Developments International

510(k) Summary

Date Prepared: 4 November 2013

510(k) Owner:
Medical Developments International Limited
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Springvale VIC 3171
Australia

Submitter/ Official Contact:
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NOV 13 2013

Device Trade Name: Space Chamber Plus
Compact Space Chamber Plus

Device Common / Classification Name: Spacer / Valved Holding Chamber; Nebulizer (Direct Patient Interface)

Device Classification: 21 CFR868.5630, Class II

Product Code: NVP

Predicate: AeroChamber Plus aVHC with Flow-Vu IFI (K070674)

Description: The Space Chamber Plus and Compact Space Chamber Plus are devices designed to assist patients with inhaling aerosolized medication dispensed through a Metered Dose Inhaler.

The devices consist of a cylindrical chamber with an opening at each end. One opening is for the aerosol medication to be inserted, the other is tapered into a mouthpiece for inhalation. The mouthpiece can be used with or without a mask.

The Compact Space Chamber Plus is a smaller version of the Space Chamber Plus that allows for easier storage and handling.

Intended Use: The Space Chamber Plus and Compact Space Chamber Plus are intended to be used by patients who are under the care or treatment of a licensed health care provider or physician. The devices are intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, prescribed by a physician or health care professional. The intended environments for use include home, hospitals and clinics.

Comparison of Technological Characteristics:

The technological characteristics of the new devices are similar to the legally marketed predicate as summarised below:

Technology	Space Chamber Plus and Compact Space Chamber Plus*	AeroChamber Plus Flow-Vu Anti-static valved holding chamber	Comparison
Valve	*Cross Slit Valve Technology:* Confirms a secure seal if the valve opens as the patient inhales and closes as the patient exhales (as observed through the clear transparent body of the spacers) indicating proper inhalation technique.	*Flow-Vu indicator:* Confirms a secure seal if the indicator moves indicating proper inhalation technique.	Both technologies provide an indication of proper inhalation technique.
Inhaler base	The orifice in the overmould component is compatible with all standard types of metered dose inhalers.	Orifice in the backpiece or inhaler base allows insertion of metered dose inhalers. Flow Signal whistle sound when inhaling too quickly	Patients inhale the amount of drug within the holding chamber. Particle size testing confirms the proposed device delivers an equivalent amount of respirable fraction compared to the predicate (see report in Attachment 1)

The Space Chamber Plus, Compact Space Chamber Plus and the predicate all use a holding chamber and one-way valve system through which metered dose inhaler medication passes to the patient.
Particle size distribution testing confirms the substantial equivalence of respirable dose delivered to the patient between the proposed devices and the predicate.

Clinical Data:

The use of Valved Holding Chambers to assist with the administration of aerosolized medication is proven technology and is well accepted by the medical community. Non-clinical data is sufficient to demonstrate the safety and efficacy of the Space Chamber Plus and Compact Space Chamber Plus devices.

Non-clinical Performance Data:

Evaluation of the new device and the predicate device was performed in accordance with the relevant sections of the CDRH Guidance Document "Reviewers Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators" (FDA/CDRH/ODF/DCRD/ADDB -1993).

Particle size distribution testing was performed using 3 drug classes ipratropium bromide (anti-cholinergic bronchodilator), albuterol (beta-agonist bronchodilator) and beclomethasone dipropionate (anti-inflammatory) comparing the Space Chamber Plus and Compact Space Chamber Plus with the predicate. The respirable fraction delivered by the spacers is greater than that delivered by the pMDI alone. The respirable fractions delivered by the Space Chamber Plus and Compact Space Chamber Plus are equivalent to those delivered by the predicate, Aerochamber Plus Flow Vu Anti-static. Likewise, the MMAD values obtained with Space Chamber Plus and Compact Space Chamber Plus are comparable to those obtained with Aerochamber Plus Flow Vu Antistatic. The 95% CI is narrow for both the respirable fraction and MMAD results, indicating that medication doses can be consistently delivered by the spacers. Particle size distribution testing confirms the proposed devices to be substantially equivalent to the predicate device.

Device	Particle size, Mean MMAD, µm (95% CI)	Mean total respirable dose, µg (95% CI)	Mean respirable fraction PF% 0.5-4.7 (95% CI)
Albuterol			
Albuterol pMDI	2.6 (0.11)	347.1 (43.3)	79.7 (3.3)
Space Chamber Plus	2.5 (0.04)	286.9 (36.3)	86.1 (0.9)
Compact Space Chamber Plus	2.3 (0.05)	253.4 (38.7)	88.0 (0.6)
Aerochamber Plus Flow Vu Anti-static	2.4 (0.03)	292.2 (19.2)	87.6 (0.7)
Ipratropium Bromide			
Ipratropium Bromide pMDI	0.72 (0.06)	51.14 (2.8)	54.7 (1.7)
Space Chamber Plus	0.93 (0.05)	85.26 (3.3)	65.3 (0.9)
Compact Space Chamber Plus	0.80 (0.02)	65.19 (2.1)	61.9 (0.7)
Aerochamber Plus Flow Vu Anti-static	0.76 (0.05)	55.28 (3.0)	60.0 (1.8)
Beclomethasone Dipropionate			
Beclomethasone Dipropionate pMDI	1.4 (0.07)	218.12 (16.3)	77.3 (2.4)

Space Chamber Plus	1.3 (0.02)	328.05 (9.9)	82.7 (0.8)
Compact Space Chamber Plus	1.3 (NA^)	308.29 (12.7)	83.7 (1.0)
Aerochamber Plus Flow Vu Anti-static	1.3 (0.03)	316.25 (17.6)	83.9 (1.1)

^ Not applicable (NA) when results for each individual run is the same

Particle size distribution testing was repeated post-cleaning. Performance testing demonstrates that the post-washed Space Chamber Plus and Compact Space Chamber Plus remain equivalent to the pre-washed devices and to the predicate device.

Other performance testing includes materials characterization, particulate analysis, drop test and cleaning validation.

ISO 10993 testing has been performed on the Space Chamber Plus components, including Cytotoxicity, Sensitization, Irritation, Genotoxicity and Implantation tests. The Space Chamber Plus and Compact Space Chamber Plus devices are made of identical materials; the Compact Space Chamber Plus is a smaller version of the Space Chamber Plus that allows for easier storage and handling.

Non-clinical and performance testing demonstrates that the Space Chamber Plus and Compact Space Chamber Plus devices raise no new issues of safety or effectiveness compared to the legally marketed predicate device.

Substantial Equivalence Conclusion:

The new devices, the Space Chamber Plus and Compact Space Chamber Plus, are considered to be substantially equivalent to the predicate device based on the following:

- they have the same intended use and are indicated for the same user population;
- they have equivalent technological characteristics to the predicate;
- they do not raise any new questions of safety or effectiveness;
- they are at least as safe and effective as the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 13, 2013

Medical Developments International Limited
Maggie Oh
Director, Scientific Affairs
7/56 Smith Road
Springvale Victoria 3171
Australia

Re: K122252
Trade/Device Name: Space Chamber Plus Compact Space Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: NVP
Dated: November 8, 2013
Received: November 12, 2013

Dear Ms. Oh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Evaluation
Center for Device and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122252

Device Name: **Space Chamber Plus**

Indications for Use:

The Space Chamber Plus is intended to be used by patients who are under the care or treatment of a licensed health care provider or physician. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, prescribed by a physician or health care professional. The intended environments for use include home, hospitals and clinics.

Device Name: **Compact Space Chamber Plus**

Indications for Use:

The Compact Space Chamber Plus is intended to be used by patients who are under the care or treatment of a licensed health care provider or physician. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, prescribed by a physician or health care professional. The intended environments for use include home, hospitals and clinics.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nayan U. Patel -S
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